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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,760	08/07/2001	Milan Mrksich	7814/45	1390

7590

05/28/2003

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EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
1641	11

DATE MAILED: 05/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/923,760

Applicant(s)

MRKSICH ET AL.

Examiner

Mary (Molly) E. Ceperley

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-117 is/are pending in the application.
- 4a) Of the above claim(s) 1-35 and 40-117 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6,10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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1) Applicants' election without traverse of Group V, claims 36-39, drawn to a protein chip, in Paper No. 9 is acknowledged. Applicants have further elected the species of protein chip in which the substrate is gold, the reactant ligand is a diethyl-*p*-nitrophenyl phosphate, and the capture polypeptide is cutinase. Claims 1-35, and 40-117 are withdrawn from further consideration as being drawn to non-elected inventions.

2) Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

3) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5) Claims 36-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

It is not clear from the specification how the final product "protein chip" of claim 36 would be used. Since the "reactant ligand" and the "fusion polypeptide" are required to form a "reaction product", it is not clear that the final "protein chip" would have a function, i.e. there is no moiety present on the "reaction product" which would further bind any molecule of interest. In the final product "protein chip",

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one member of a specific binding pair (the "reactant ligand") has already been bound to its corresponding second member (the "fusion polypeptide").

6) Claims 36-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There is no enablement in the specification for how to make and use the "protein chips" of claims 37-39 wherein the recited elements are present *in addition to* the elements recited in claim 36 (see paragraph 7) below). The specification is enabling only for the preparation and use of the protein chips of claims 37-39 wherein the elements (i) and (ii) of claims 37-39 *further define* the elements recited in claim 36.

7) Claims 36-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear from the "further comprising" wording of claims 37-39 whether the additional recited elements are present *in addition to* the basic "protein chip" or whether these elements *further define* the basic structure of claim 36. If these elements are *additional* elements, the claims are indefinite in not reciting the structural relationship of the additional elements to the basic elements recited in claim 36. If these elements *further define* the basic structure of claim 36, it is suggested that appropriate "wherein" language be used; for example, "the protein chip of claim 36 wherein the substrate comprises a gold surface and...".

8) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9) Claims 36-39 are rejected under 35 U.S.C. 103(a) as being obvious over (a) Mrksich (Chem. Soc. Rev., 2000, 29, 267-273) taken in combination with (b) the admitted prior art as set forth at page 15 of the specification.

Mrksich describes self-assembled monolayer (SAMs) biosensors formed on a gold substrate in which a peptide ligand is attached to the gold through an alkanethiolate-polyethylene glycol linkage. A variety of types of ligand combinations are described as being appropriate for attachment to SAMs. See page 269, second column, the last three sentences under "Biospecific recognition": Ni(II)/his-tagged proteins, d-Ala-d-Ala/vancomycin, and biotin/streptavidin ligand combinations. The alkanethiolate-polyethylene glycol linkages of the reference as shown in Figure 5 are the same as those described in instant claims 37-39 (-S-L-Q-) and in the reaction scheme of page 71 of the instant specification. The reference does not specifically describe cutinase/nitrophenylphosphate as a ligand combination.

The admitted prior art as set forth in Table A of page 15 of the instant specification establishes that His-tag polypeptide/quinone-NTA and cutinase/nitrophenylphosphonates are both reactant ligand/capture polypeptide pairs which are well known in the art.

Given the teaching of Mrksich that a variety of ligand combinations including Ni(II)/his-tagged protein are suitable for attachment to polyethylene glycol-alkanethiolate linkers on gold substrates, it would be obvious to substitute another well known equivalent ligand combination, i.e. cutinase/nitrophenylphosphonate, on the Mrksich SAM, as claimed, with the expectation of obtaining a similarly useful biosensor. Note that claims 36-39 are not limited to the use of any particular ligand/fusion polypeptide combination.

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**10)** Claims 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over **(a)** Yousaf et al (J. Am. Chem. Soc. **1999**, **121**, 4286-4287) taken in combination with **(b)** the admitted prior art as set forth at page 15 of the instant specification.

Yousaf et al describe self-assembled monolayer (SAMs) biosensors formed on a gold substrate in which a peptide ligand is attached to the gold through an alkanethiolate-polyethylene glycol linkage. See the title, the first paragraph of the article, and Figure 1.

The admitted prior art as set forth in Table A of page 15 of the instant specification establishes that His-tag polypeptide/quinone-NTA and cutinase/nitrophenylphosphonates are both reactant ligand/capture polypeptide pairs which are well known in the art.

Given the teaching of Yousaf et al that peptides are suitable as ligands for attachment to polyethylene glycol-alkanethiolate linkers on gold substrates used as biosensors, it would be obvious to substitute another well known equivalent ligand combination, i.e. cutinase/nitrophenylphosphonate, on the SAM of Yousaf et al, as claimed, with the expectation of obtaining a similarly useful biosensor. Note that claims 36-39 are not limited to the use of any particular ligand/fusion polypeptide combination.

**11)** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399. The fax phone number for responses to be filed BEFORE final rejection is (703) 872-9306. The fax phone number for responses to be filed AFTER final rejection is (703) 872-9307.

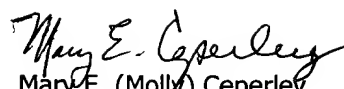
Questions which are NOT RELATED TO THE EXAMINATION ON THE MERITS, should be directed to **TC 1600 CUSTOMER SERVICE** at **(703) 308-0198**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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May 27, 2003

  
Mary E. (Molly) Ceperley  
Primary Examiner  
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